GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON SENIOR SCIENTIST AWARD (K05) APPLICATIONS

PA NUMBER: PA-00-021

Complete details at: http://grants.nih.gov/grants/guide/pa-files/PA-00-021.html

The Senior Scientist Award (K05) provides stability of support to outstanding scientists who have demonstrated a sustained, high level of productivity and whose expertise, research accomplishments, and contributions to the field have been and will continue to be critical to the mission of the particular NIH center or institute. The award provides salary support for award periods of up to five years as a means of enhancing the individual recipient's skills and dedication to his/her area of research. The Senior Scientist Award permits NIH institutes and centers to identify and support exceptionally talented investigators who are well established in their field of research.

General Considerations when reviewing K05 applications:

- Candidates must be a senior scientists and recognized leaders in the field with distinguished records of original contributions
- Must have a record of support from a funding institute or center
- Must have peer-reviewed grant support at the time of the award
- Scientists whose work is primarily theoretical may, depending on the policy of the institute or center, apply for this award in the absence of research grant support
- Applications may be submitted on behalf of candidates by domestic, non-Federal organizations, public or private, such as medical, dental, or nursing schools or other institutions of higher education

CRITIQUE

Each major review element within the Senior Scientist Award application (Candidate, Career Development and Research Plan, Institutional Environment and Commitment to the Candidate) should be commented on in a separate section of your written critique. For revised applications, also comment briefly on whether the application is improved, the same, or worse. In addition, provide a one-sentence summary of your evaluation at the end of each section. After considering all of the review criteria, briefly summarize the strengths and weaknesses of the application and recommend an overall level of merit in a section titled Summary and Recommendations (see below). Please note that your comments will be used essentially unedited in the final summary statement sent to the candidate.

Candidate

- A consistent record of outstanding research productivity including program research funding and record of publication of scientific reports, including publication of influential research papers or seminal theoretical papers
- Recognition as a leading senior scientist as judged by peers
- Leadership of a productive research program
- Ability to develop and maintain a high quality environment for training and mentoring investigators

- The candidate's current involvement in science education, science advocacy, and scientific integrity training
- The extent to which the award will enable the candidate to devote full-time to research and research-related activities and will permit release from teaching, administrative, clinical, and other non-research related responsibilities
- Likelihood of continuing and significant contributions to scientific knowledge.

Career Development and Research Plan

- Scientific and technical merit of the research plan
- Significance of the research plan and the probability of significant contributions to scientific knowledge
- Long-term substantive plan for future research
- Consistency of the career development plans with the candidates' career goals
- Quality of plans for mentoring and science education activities
- Adequacy of plans to include children, women, and minorities in any planned clinical studies.

Institutional Environment and Commitment to the Candidate

- Adequacy of the facilities and general environment as it relates to the proposed research and career development program
- Availability of collaborative opportunities with other investigators
- Reputation of the applicant institution and the candidate's department as a center of active, high-quality research
- Institutional support of the candidate's commitment to research and research training

SUMMARY AND RECOMMENDATION

In one paragraph, briefly summarize the most important points of the Critique, addressing the strengths and weaknesses of the application in terms of the six review criteria. An application does not need to be strong in all categories to receive a good rating. Each scored application will receive a numerical rating that will reflect your opinion of its merit. The numerical rating is based on a scale from 1.0 for the most meritorious to 5.0 for the least meritorious with increments of 0.1 unit. Reviewers should score the "average" application they customarily review in their Scientific Review Group with a score of 3.0. This practice is designed to have 3.0 be the median.

Protection of Human Subjects from Research Risks: Evaluate the application with reference to the following criteria: risk to subjects, adequacy of protection against risks, potential benefit to the subjects and to others, importance of the knowledge to be gained. (If the applicant fails to address **all** of these elements, notify the SRA immediately to determine if the application should be withdrawn.) If all of the criteria are adequately addressed, and there are no concerns. Write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. If the application indicates that the proposed human subjects research is exempt from coverage by the regulations, determine if adequate

justification is provided. If the claimed exemption is not justified, indicate "Unacceptable" and explain why you reached this conclusion. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRA immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

Inclusion of Women Plan:
Inclusion of Minorities Plan:
Inclusion of Children Plan:
Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4. Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

Category	Gender (G)	Minority (M)	Children (C)
1	Both Genders	Minority & non-minority	Children & adults
2	Only Women	Only minority	Only children
3	Only Men	Only non-minority	No children included
4	Gender unknown	Minority representation unknown	Representation of children unknown
5		Only Foreign Subjects	

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate.

Vertebrate Animals: Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

Biohazards: Note any materials or procedures that are potentially hazardous to research personnel and indicate whether the protection proposed will be adequate.

OTHER CONSIDERATIONS: These comments are useful to NIH but should not influence your overall score.

Foreign Training: In a separate section, describe the scientific advantages of the proposed training in a foreign country and compare it to relevant training opportunities available in this country. Comment on any special talents, resources, populations, or environmental conditions that are not readily available in the United States or that augment existing resources. This consideration should not be factored into your overall recommendation and rating.

Administrative Note: (e.g., There is potential overcommitment and/or scientific overlap with other existing grants and/or pending applications.)

Data Sharing Plan: Applications requesting more than $500,000 direct costs in any year of the proposed research are expected to include a data sharing plan in their application. Certain Program Announcements may request a data sharing plan for all applications regardless of the amount of direct costs. Assess the reasonableness of the data sharing plan or the rationale for not sharing research data.

Model Organism Sharing Plan: The NIH policy on sharing of model organisms for biomedical research was announced in the May 7, 2004 issue of the NIH Guide (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html). Starting with the October 1, 2004 receipt date, all new and competing-renewal NIH grant applications that plan to produce model organisms will be expected to include a sharing plan. Unlike the NIH Data Sharing Policy, the submission of a model organism sharing plan is NOT subject to a cost threshold of $500,000 or more in direct costs in any one year, and is expected to be included in all applications where the development of model organisms is anticipated.

Budget: Evaluate the direct costs only. Do not focus on detail. For all years, determine whether all categories of the budget are appropriate and justified. Provide a rationale for each suggested modification in amount or duration of support.

Further information about NIH research training and career development opportunities can be found at http://grants.nih.gov/training .

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